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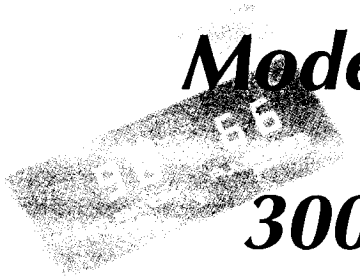
Model 300 Series

Pulse Oximeter User's Manual



Models

300

305

305A

305AC

340

PALCO LABORATORIES

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TABLE OF CONTENTS

1 PRINCIPLES OF OPERATING THE MODEL 300 SERIES PULSE OXIMETERS 1

1.1 INTENDED USES 1

1.2 PRINCIPAL FEATURES 1

1.3 MODES OF MONITORING 2

1.4 CAUTIONS 2

2 KEYS, INDICATORS, SYMBOLS & MARKINGS 3

2.1 KEYS & INDICATORS 3

2.2 SYMBOLOGY & MARKINGS ..... -

3 OPERATING THE MODEL 300 SERIES 9

3.1 RECEIVING ACCURATE READINGS 9

3.2 POWER 9

3.2.1 MODEL 300 9

3.2.2 MODELS 305 THROUGH 340 10

3.3 MEASURING AND DISPLAYING PULSE OXIMETRY 10

3.3.1 SPOT-CHECK PULSE OXIMETRY 10

3.3.2 CONTINUOUS-MONITORING PULSE OXIMETRY 11

3.4 DATA TRANSMISSION (MODELS 305A, 305AC, 340) 11

3.4.1 SERIAL DATA TRANSMISSION 11

3.4.2 ANALOG DATA TRANSMISSION 12

3.5 TESTS 12

3.5.1 MODEL 300 THROUGH 305AC 13

3.5.1.1 POWER-UP TEST 13

3.5.1.2 INTERNAL CONFIDENCE TESTS 13

3.5.1.3 SELF DIAGNOSTIC TESTS 13

3.5.2 MODEL 340 14

3.5.2.1 POWER-UP TEST 14

3.5.2.2 INTERNAL CONFIDENCE TESTS 14

3.5.2.3 DIAGNOSTIC TESTS 14

3.6 CLEANING INSTRUCTIONS 16

3.7 TROUBLESHOOTING 17

TABLE OF CONTENTS (CON'T)

4 EQUIPMENT SPECIFICATIONS 18

4.1 OXYGEN SATURATION AND PULSE RATE 18

4.2 ALARMS (MODEL 340 ONLY) 18

4.3 GENERAL 18

4.4 SENSORS 18

4.5 POWER SOURCE 18

4.5.1 MODEL 300 18

4.5.2 MODELS 305 THROUGH 340 18

4.6 ENVIRONMENTAL CONDITIONS 19

4.7 EQUIPMENT CLASSIFICATION 19

5 ORDER INFORMATION 20

5.1 PRODUCT INFORMATION 20

5.2 CONTACT CUSTOMER SERVICE INFORMATION 20

6 WARRANTY INFORMATION 21

6.1 APPLICABILITY OF WARRANTY 21

6.2 WHAT IS COVERED BY THIS WARRANTY 21

6.3 WHAT PALCO WILL DO TO CORRECT PROBLEMS 21

6.4 OWNER'S REGISTRATION 22

6.5 PRODUCT INFORMATION 22

7 DECLARATION OF CONFORMITY 23

1. PRINCIPLES OF OPERATION OF THE 300 SERIES PULSE OXIMETERS

The Model 300 Series comprises the following pulse oximeters:

Models 300, 305, 305A, 305AC & 340.

Before using the pulse oximeter, the user should become thoroughly familiar with the information in this manual and with all information included with the sensor.

1.1 INTENDED USES

- The Models 300 and 305 are intended for spot checks.
- Models 305A and 305AC are used for data transmission to another monitoring device such as in sleep laboratory monitoring systems. The units do not have alarms, and are not intended for continuous monitoring.
- The Model 340 is the only pulse oximeter intended for continuous monitoring.

WARNING: Do not use the pulse oximeter as an infant apnea alarm.

1.2 PRINCIPAL FEATURES

All Models

- The PALCO Labs Model 300 Series Pulse Oximeters are portable, lightweight instruments designed to monitor arterial oxygen saturation non-invasively.
- All models have two bright Light Emitting Diode (LED) displays that give a constant read-out of oxygen saturation (in $\%SpO_2$) and pulse rate in beats-per-minute ♥/min (BPM).
- Each machine has a front-panel LED INDICATOR that alerts the user to a low-battery condition.
- All Model 300 Series Pulse Oximeters perform a functional test at power-on, and diagnostics tests can be initiated.
- All PALCO oximetry sensors with RJ12 connectors are compatible with the Model 300 Series.
- All the pulse oximeters can be powered either by standard electric power or an internal, rechargeable Nickel-Cadmium (NiCad) battery — except the Model 300, which is powered solely by six [6] type "AA" batteries.

Model 305A and Model 340

- The Models 305A and 340 allow for data transmission through the data port (when Serial or Analog Cable is plugged in at power-up), while heart rate and $\%SpO_2$ are displayed on the Oxygen Saturation and Pulse Rate displays.

Model 305AC

- The Model 305AC allows for data transmission through the data port while the two LED displays dim after five (5) minutes of operation.
- The Model 305AC is the only unit that does not power off automatically when operating on battery power.

Model 340

- The Model 340 has visual and audible alarms for oxygen saturation and pulse rate monitoring.

•The Model 340 has an audible tone that sounds with each pulse and varies with oxygen saturation -- falling in pitch with reduced saturation and rising as saturation increases.

1.3 MODES OF MONITORING

All Models

•All models in the PALCO Labs 300 Series are calibrated to measure the oxygen saturation (%SpO_2) of functional hemoglobin.

•A normal (steady) display indicates the oximeter has received at least three normal, intelligible pulses during the last 30-second period. The display will be updated each time a normal pulse has been received.

•A blinking display indicates the continuous presence (30 seconds or more) of significant patient movement or light-source interference. In this mode, no normal pulses are being received, and the last reliable values for %SpO_2 and pulse rate are displayed. In this mode, %SpO_2 monitoring may be adversely affected.

Model 340

•A blinking display with a one-second warning tone every 10 seconds indicates the continuous presence (60 seconds or more) of significant patient movement or light-source interference. In this mode, no normal pulses are being received and %SpO_2 monitoring may be adversely affected.

1.4. CAUTIONS

•Before using the equipment, the operator should be thoroughly familiar with the information in the User's Manual and all accompanying documents.

•Federal (U.S.A.) law restricts this device to use by — or on the order of — a physician.

•The instrument should not be used in the presence of anesthetics or flammable agents.

•Do not allow any liquid to penetrate the instrument's interior.

•The Model 300 Series Pulse Oximeters are designed to operate in normal, ambient light conditions.

•Do not use near Magnetic Resonance Imaging equipment.

•To avoid potential effects of electromagnetic interference, maintain a distance of at least 15 cm. (6") between the oximeter and other devices. Also, maintain a distance of at least 20 cm. (8") between the PALCO Labs wall adaptor and other devices.

•When used with other equipment, such as a defibrillator, the accuracy of pulse oximetry readings may be affected.

•In case of abnormal conditions during instrument operation, appropriate measures (such as powering off instruments) should be taken to insure patient safety.

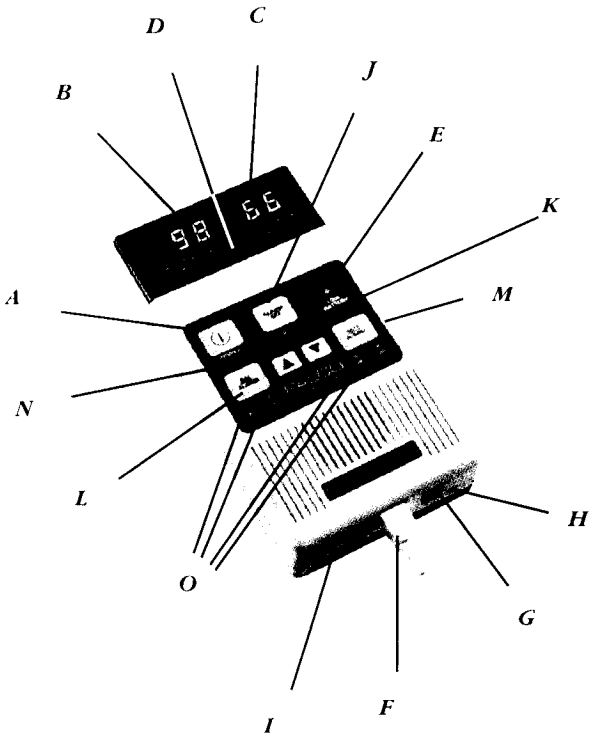
•The user should **NOT** attempt to modify or repair the instrument.

•This device complies with Electromagnetic Compatibility standards EN55011 and EN60601-1-2. If the user experiences interference problems, move the unit away from other EMC emitting equipment.

•Dispose of this device according to hospital and/or governmental regulations.

2. KEYS, INDICATORS, SYMBOLS AND MARKINGS

2.1 KEYS AND INDICATORS



A. POWER ON/OFF KEY

All Models

The unit is powered on with a short depression of the POWER ON/OFF KEY. A one-second display and indicator test is performed automatically, and all Light Emitting Diodes (LEDs) are illuminated. Carefully observe the Saturation and Pulse Rate LED displays at the top of the oximeter for proper operation of all segments of the display; a nonfunctioning segment will result in an incomplete numeral and possible erroneous reading. A long depression of the POWER ON/OFF KEY will initiate Internal Confidence and Self Diagnostics tests (See Section 3.5 "Tests").

B. OXYGEN SATURATION DISPLAY

All Models

Whenever the pulse oximeter receives at least three (3) pulses during a 30-second period, the left LED shows the patient's $\%SpO_2$ levels. The display is updated with every normal pulse. A blinking display signals that $\%SpO_2$ monitoring may be adversely affected, and indicates the continuous presence (30 seconds or more) of significant patient movement or light-source interference.

Model 305AC

The Model 305AC dims the display after five (5) minutes of operation when the Serial or Analog Cable is connected to the unit at power-up. The display can be reactivated for five (5) minutes by pressing the POWER ON/OFF KEY.

C. PULSE RATE DISPLAY

All Models

Whenever the pulse oximeter receives at least three (3) pulses during a 30-second period, the right, three-digit LED displays the patient's heart rate in beats-per-minute ♥/min (BPM). Any blinking display signals that pulse rate monitoring may be adversely affected, and indicates the continuous presence (30 seconds or more) of significant patient movement or light-source interference.

Model 305AC

The Model 305AC dims the display after five (5) minutes of operation when the Serial and Analog Cable is connected to the unit at power-up. The display can be reactivated for five (5) minutes by pressing the POWER ON/OFF KEY.

D. VISUAL PULSE INDICATOR

All Models

As soon as a pulse is found, the heartbeat is indicated by the small green LED beneath the LED display window. The VISUAL PULSE INDICATOR simultaneously flashes with the patient's pulse. It will typically begin to flash a few seconds before numerical values for oxygen saturation and pulse rate are shown.

E. LOW BATTERY INDICATOR

All Models

The LOW BATTERY INDICATOR will illuminate when the battery is near depletion, prompting the user to suspend operation of the unit and change or recharge the battery (using the method described in Section 3 "Power"). The oximeter will automatically power off shortly after low-battery indication. The acronym bAt LO will be displayed if power-on is attempted during a low-battery condition.

F. SENSOR CABLE CONNECTION

All Models

All PALCO Labs pulse oximetry sensors with RJ12 connectors are compatible with the Model 300 Series. To connect a sensor to the oximeter, align the plug with the jack on the oximeter and insert it gently until an audible "click" is heard — indicating that the plug tab is latched in place. To remove, squeeze the locking tab on the plug and slide the plug out of the jack. Always route cords in such a way as to prevent accidental tripping and subsequent damage to the oximeter.

G. POWER CONNECTION

Model 305, Model 305A, Model 305AC, Model 340

For electric power, plug the adaptor into the pulse oximeter's POWER CONNECTION, and then plug the other end of the adaptor into a standard electrical outlet. **All PALCO Labs Pulse Oximeters (except for the Model 300) were designed to be used with the adaptor provided by PALCO Labs at the time of purchase.**

H. POWER INDICATOR

Model 305, Model 305A, Model 305AC, Model 340

The green LED — located on the bottom of the oximeter adjacent to the POWER CONNECTION — will illuminate when electric power is connected.

I. DATA PORT

Model 305A, Model 305AC, Model 340

The DATA PORT is used for serial and analog output. To eliminate risk of shock, take care not to touch the DATA PORT 8-pin Connector and the patient simultaneously. The DATA PORT should be used only for connection to equipment that complies with CSA/IEC/UL601-1. Refer to Section 3 for information on Data Transmission.

J. ALARM OFF KEY

Model 340

A short depression of this key silences the alarm for a period of 60 seconds. A long, three-second depression of the ALARM OFF KEY will completely disable the audible alarm. The LED display will show AL OFF, the ALARM OFF INDICATOR will begin to flash, and the oximeter will revert to normal monitoring. Silenced alarms can be reactivated by a short depression of the ALARM OFF KEY. Disabled alarms are reactivated by a long depression of the ALARM OFF KEY.

K. ALARM OFF INDICATOR

Model 340

The ALARM OFF INDICATOR will illuminate and remain on constantly when audible alarms are silenced, and will flash when audible alarms are disabled.

L. OXYGEN SATURATION ALARM KEY

Model 340

Short depressions of the OXYGEN SATURATION ALARM KEY will toggle the display between the high and low alarm settings, as shown by the *HI/LO ALARM INDICATORS*. These alarm settings can be adjusted with the INCREMENT ▲ and DECREMENT ▼ KEYS. The alarm settings will be retained in memory until reset by the user. Exception: When the low-saturation alarm is set below 80%, it will return to 80% at the next power-up. The saturation alarm production settings are: High 100% and Low 85%. The high-saturation alarm can be disabled by setting it at 100%. The unit reverts to normal monitoring after a five-second period of key inactivity.

M. PULSE RATE ALARM KEY

Model 340

Short depressions of the PULSE RATE ALARM KEY will toggle the display between the high and low alarm settings as shown by the indicators (HI and LO) below the key. These alarm settings can be adjusted via the ▲ and ▼ keys. Alarm settings will be retained in memory until they are changed by the user. The pulse-rate alarm production settings are: High 140 BPM (♥/min) and Low 50 BPM (♥/min). The display reverts to normal patient monitoring after a five-second period of key inactivity.

N. INCREMENT & DECREMENT KEYS ▲ ▼

Model 340

The pulse-tone volumes can be adjusted using the INCREMENT ▲ and DECREMENT ▼ KEYS. There are three (3) levels of audible (pulse) tone volume, and "off." The pulse tone volume can be increased with the ▲ key, and decreased or silenced with the ▼ key. Alarm levels are also adjusted with these keys.

O. VISUAL HI/LO ALARM INDICATORS HI LO

Model 340

Located beneath the OXYGEN SATURATION ALARM and PULSE RATE ALARM KEYS, these indicators illuminate when the patient's oxygen saturation or pulse rate reaches the preset high or low alarm settings. In order to set alarms, the appropriate indicator must be illuminated.

ADDITIONAL FEATURES

AUDIBLE OXYGEN SATURATION INDICATOR

Model 340

A varying pitch of the audible tone signals a change in the $\%SpO_2$ level — a falling pitch indicates a decreasing $\%SpO_2$ level.

AUDIBLE PULSE RATE INDICATOR

Model 340

A beeping audible tone signals the heart beat.

AUDIBLE ALARM INDICATORS

Model 340

The alarm tone is a fixed pitch, and the volume cannot be adjusted. Alarm conditions are generated only when a pulse has been detected. Alarm tones are automatically silenced when the alarm condition goes away. HIGH PRIORITY alarm tones sound continuously at the highest frequency and highest volume. HIGH PRIORITY alarms are caused by conditions such as: low and high oxygen saturation and pulse rate; no pulse; excessive ambient light; and other error conditions. MEDIUM PRIORITY alarm tones sound for 0.75 (¾) seconds every five (5) seconds at the highest frequency and highest volume. MEDIUM PRIORITY alarms are cause by measuring problems such as disconnected sensor, too thin or thick tissue, or a faulty sensor. LOW PRIORITY alarm tones sound for one (1) second every 10 seconds at the lowest frequency and highest volume. LOW PRIORITY alarms are caused by excessive patient movement or patient arrhythmia.

BATTERY COMPARTMENT (& BATTERY POLARITY ⊖ ⊕)

Back of Model 300

The compartment houses the six (6) type "AA" batteries necessary to power the Model 300. Be sure to correctly install the batteries by following the polarity indicated inside the compartment.

2.2 SYMBOLOGY & MARKINGS

Symbol	Definition
$\%SpO_2$	Oxygen Saturation Percentage
♥/min	Heart Beats per Minute (BPM)
	Power On/Off
	Alarm Off
	Low Battery Indicator
	Oxygen Saturation Alarm
	Pulse Rate Alarm
HI LO	HI/LO Alarm Indicator
▲	Increment Key

Decrement Key

Data Port

Sensor Cable Connection

Power Connection

Attention: Consult Accompanying Documents

Non-anesthetic Proof

Type BF Applied Part

Battery Polarity

3. OPERATING THE MODEL 300 SERIES

WARNING: To ensure personal safety and proper operation of the oximeter, the user should adhere to all directions, information, and cautions stipulated within this document.

3.1 RECEIVING ACCURATE READINGS

WARNING: In order to obtain accurate pulse oximetry readings, an appropriate pulse oximeter and sensor need to be chosen according to the intended use. *All instructions stated within this manual* and included with each sensor should be followed.

To prevent faulty readings and sensor complications:

- •do not apply the sensor to anything but a well-perfused extremity.
- •do not place the sensor on extremities with blood pressure cuffs or with arterial or venous catheters.
- •avoid extremity positions that may compress venous return.
- •keep sensors at heart level whenever possible.
- •fit sensors comfortably without constricting or compressing digits.
- •do not restrict circulation with elastic tape used to secure sensors.
- •trim long fingernails if necessary.
- •remove artificial nails and thick nail polishes if necessary.
- •check for intravascular dyes, which may affect pulse oximeter readings.
- •turn off very bright lights, such as xenon lamps, if they interfere with sensor functioning. In cases where such lights are unavoidable, cover the sensor site with an opaque material.
- •route sensor cords carefully.
- •avoid applying excessive tension to the sensor or sensor cable.
- •consider conditions affecting the hemoglobin dissociation curve when interpreting pulse oximeter readings.
- •keep patient movement to a minimum.

3.2 POWER

3.2.1 Model 300

The Model 300 is powered solely by six (6) type "AA" alkaline batteries. The instrument will operate for approximately 16 hours (approximately 2,000 spot checks) before the LOW BATTERY INDICATOR signals that the batteries need to be replaced.

NOTE: Remove the batteries prior to storage if the oximeter is not likely to be used for an extended period of time.

3.2.2 Model 305, Model 305A, Model 305AC, Model 340

All of these pulse oximeters can be powered by either a power adaptor or the internal, rechargeable NiCad battery. Battery operation alone will provide the oximeter with approximately 12 hours of continuous operation. To charge the internal NiCad battery, connect the PALCO Labs power adaptor to the POWER CONNECTION located at the bottom of the oximeter. Then, plug the adaptor into an appropriately rated electrical outlet. The green POWER INDICATOR will illuminate. Once electric power is applied, the battery will charge regardless of the operational state of the oximeter.

WARNING: *All PALCO Labs Pulse Oximeters (except for the Model 300) were designed to be used with the power adaptor provided by PALCO Labs at the time of purchase. The use of any other adaptor may damage the oximeter and will void the PALCO Labs Warranty. Refer to the product number of the power adaptor when reordering a new adaptor. Include the serial number of the unit as this allows PALCO Labs to determine the adaptor needed. Also, avoid excess tension on the adaptor cable for safe and continuous operation.*

3.3 MEASURING AND DISPLAYING PULSE OXIMETRY

WARNING: Patient movement, light-source interference, or any other *disturbing causes that occur for more than 30 seconds are displayed by a blinking display. During this period, pulse oximeter readings can be adversely affected.*

3.3.1 Spot-Check Pulse Oximetry

·Choose an appropriate pulse oximeter and sensor according to the intended use.
·Place the sensor according to the instructions included with each sensor.
·Connect the sensor to the pulse oximeter with the SENSOR CABLE CONNECTION.
·Follow all guidelines to prevent faulty readings, and oximeter or sensor complications.
·Power on the unit with the POWER ON/OFF KEY.
·Check that all LEDs illuminate during the Power-Up Test.
·Monitor the flashing of the VISUAL PULSE INDICATOR.
·Read patient's oxygen saturation level and pulse rate from the two LED displays.

NOTE: The unit powers off automatically when a pulse search is unsuccessful while operating on battery power.

WARNING: The Models 300, 305A, and 305AC have no audible alarms. Each model is intended for use by an attending clinician and should not be used in situations where alarms are required.

3.3.2 Continuous-Monitoring Pulse Oximetry

Model 340

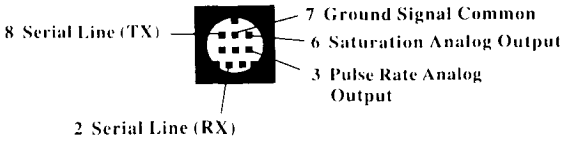
·Choose an appropriate sensor.
·Place the sensor according to the instructions included with each sensor.
·Connect the sensor to the pulse oximeter with the SENSOR CABLE CONNECTION.
·Follow all guidelines to prevent faulty readings, and oximeter or sensor complications.
·Power on the unit with the POWER ON/OFF KEY.
·Check that all LEDs illuminate during the Power-Up Test.
·Monitor the flashing of the VISUAL PULSE INDICATOR.
·Read the patient's oxygen saturation level and pulse rate from the two LED displays.
·Listen to the AUDIBLE OXYGEN SATURATION and PULSE RATE INDICATOR.
·Adjust the tone with the INCREMENT and DECREMENT KEYS.
·Set the VISUAL and AUDIBLE ALARMS to the desired level with the INCREMENT/DECREMENT KEYS after the OXYGEN SATURATION ALARM or PULSE RATE ALARM KEYS have been selected.
·Read the alarm settings with the HI/LO ALARM INDICATORS.
·Quell an alarm with the ALARM OFF KEY.
·Reactivate silenced alarms with the ALARM OFF KEY.

WARNING: Do not silence the audible alarms or decrease their volume if patient safety could be compromised.

3.4 DATA TRANSMISSION

Models 305A, 305AC, 340

Serial and analog data can be communicated through the data port to a peripheral device. Analog output of oxygen saturation (0-100 %SpO_2) and pulse rate (0-250 BPM) are each transmitted on a scale of 0.0 to 1.0V. Serial output of oxygen saturation (0-100 %SpO_2) and pulse rate (0-250 BPM) are transmitted once per second in a data packet. For tests regarding data transmission and the data port, please refer to the Test section.



3.4.1. Serial Data Transmission

·Serial data can be transmitted with a PALCO Labs Serial Cable.
·Transmission speed is 9600 baud.
·The data field is 8 bits, one stop bit, no parity.
·The data packet output by the Model 340 is comprised of four (4) data bytes sent in the following order: the Status byte, the %SpO_2 byte, the Pulse Rate byte, and the Checksum byte.

The Status Byte

The Status byte contains flags as to the operational state of the unit:

Bit 7: Not used.

Bit 6: Pulse is lost, having previously been detected.

Bit 5: Pulse detected, normal monitoring begun.

Bit 4: Error flag, indicating that an error is occurring.

Bit 3 to 0: Number of bytes in the data packet.

The %SpO_2 Byte

The %SpO_2 byte contains the current oxygen saturation level in %SpO_2 and is in 8-bit binary format.

The Pulse Rate Byte

The Pulse Rate byte contains the current pulse rate in BPM and is in 8-bit binary format.

The Checksum Byte

The Checksum byte is the complement to the lower eight (8) bits of the bytewise addition of the Status, SpO_2 and Rate Bytes, plus one.

3.4.2 Analog Data Transmission

·Analog data can be transmitted with a PALCO Analog Cable in Models 305A, 305AC, and 340.

·Analog outputs are as follows:

0% Scale	0.000V
50% Scale	0.500V
100% Scale	1.000V

·Model 305AC Dimming Feature:

The Model 305AC dims the display after five (5) minutes when the analog cable is installed at power-on. To restore the display for another five (5) minutes, press the POWER ON/OFF KEY. In order to power off the unit, press the POWER ON/OFF KEY when the display is active.

NOTE: Refer to the manufacturer of the monitoring device for additional information on data-receiving devices.

3.5 TESTS

Each model can perform a variety of tests, which are described below. If an error is detected during any given sequence, the test sequence will be terminated and the characters Err (an acronym for "error") will appear in the left display window. The numeral representing the test during which the error occurred will appear in the right display window. The instrument must be powered off before testing or monitoring can continue. If there is a low-battery condition at power-up, the unit will show bAt LO and the oximeter will power off, prohibiting test functions.

NOTE: Some tests require audible, visual and/or operator supervision, and/or the connection of an external device such as a sensor or voltmeter. The absence of required peripheral devices will result in an error message. Please read each of the test descriptions carefully.

3.5.1 Model 300, Model 305, Model 305A, Model 305AC

3.5.1.1 Power-Up Test

A short depression of the POWER ON/OFF KEY initiates a one-second **Display and Indicators Test.** All LEDs need to be illuminated for proper LED functioning.

3.5.1.2 Internal Confidence Tests

A long depression (approximately three [3] seconds) of the POWER ON/OFF KEY will power on the instrument, test the **Display And Indicators, Power Condition** and **EEPROM (305A, 305AC only)**, and then display the unit's **Software Version Number**. The Models 305A and 305AC will then perform an **Analog Output Test.**

EEPROM TEST

This test is automatically initiated by the self diagnostic test sequence. A successful test is shown by the display 128.

ANALOG OUTPUT TEST

The use of a voltmeter is required to perform this test. First, connect one lead to pin #6 (saturation analog output) and the common output lead to pin #7 (ground signal common). Once initiated, each depression of the ALARM OFF KEY tests the three (3) saturation values, which are displayed in the left window in ascending order. Observe the meter display to confirm a proper operation as listed below. Then connect the first lead pin #3 (pulse rate analog output) to test the three (3) pulse rate values as they are displayed in the right window.

%$Sp0_2$		Pin #6	BPM		Pin #3
0%	=	0.000V ± .001	0	=	0.000V ± .001
50%	=	0.500V ± .010	125	=	0.500V ± .010
100%	=	1.000V ± .020	250	=	1.000V ± .020

3.5.1.3 Self Diagnostic Tests

A prolonged (10-second) depression of the POWER ON/OFF KEY is required at power-on to initiate the self-diagnostic test mode. While pressing the POWER ON/OFF KEY, the unit cycles through the **Internal Confidence Tests,** blanks the display for approximately five (5) seconds, and displays the acronym tSt (an acronym for "test"). The POWER ON/OFF KEY needs to be released at this time to initiate automatic testing of **Sensor, Reference Voltage,** and **Set-Up**.

SENSOR TEST — Test # 1

This test verifies the functionality of the sensor, the oximeter's LED driver circuit, and the oximeter's light-detection circuit. This occurs by the emission of sensor light at a preset frequency and level, and the monitoring of the received signal from the sensor detector.

NOTE: An operational sensor must be connected to the oximeter to perform the Sensor Test.

REFERENCE VOLTAGE TEST — Test # 2

It takes 10 seconds to determine "Pass" or "Fail," verifying the unit's internal reference voltage. A failure is indicated by a display of E r r 2 and a pass is indicated by the next test being performed. If a failure is indicated, refer to the PALCO Labs Warranty for servicing instructions.

SET-UP TEST — Test # 3

This test alternately displays %SpO_2, pulse rate and internal circuitry set-up values. As with normal monitoring, initiate the test with a sensor applied to a subject. The instrument will perform normal set-up and monitoring functions, and will periodically display single digit set-up numbers — zero (0) for thin tissue, one (1) for medium tissue, or two (2) for thick tissue. This test can only be exited by powering off the instrument.

3.5.2 Model 340

3.5.2.1 Power-Up Test

A short depression of the POWER ON/OFF KEY initiates a one-second **Display and Indicators Test**. All LEDs need to be illuminated for proper LED functioning.

3.5.2.2 Internal Confidence Tests

A long depression (approximately three [3] seconds) of the POWER ON/OFF KEY will power on the instrument, test the **Display and Indicators**, **Power Condition** and **EEPROM**, and then display the unit's **Software Version Number**. The instrument will revert to the normal power-on sequence upon release of the POWER ON/OFF KEY.

3.5.2.3 Diagnostic Tests

Diagnostic Tests in the Model 340 can be run automatically or be initiated manually. They are initiated by first holding down the ALARM ON/OFF KEY and then powering on the unit. Upon initialization, the characters t S t will appear in the left display window and the numeral 0 in the right display window. Any test may be selected via the ▲ or ▼ front panel keys. The selected test will be represented by a numeral in the right display window. Upon selection, the sequence is initiated by the depression of the ALARM ON/OFF KEY. The test sequence will run and stop automatically. It must be noted that for a number of these tests visual and/or audio inspection is required. While in this test mode, either a single test or a batch containing all of the tests sequentially may be run. Once testing is complete, the only way to exit the assurance test mode of operation is by powering off the instrument.

SUGGESTION: Write down the instrument's software version number (in the space provided in the "Product Information" section of this manual) so PALCO Labs can better assist you in the future.

GLOBAL TEST — Test # 0

This test automatically initiates *all* of the diagnostic tests, which will run automatically and in order until either an error is detected or all test sequences are completed.

DISPLAY AND INDICATOR TEST — Test # 1

The instrument's LED displays and indicators are tested by this sequence. Upon initialization of this test, the LED display segments and discrete LED indicators will be illuminated one at a time. The user should observe proper operation of all LED segments and indicators. Careful visual inspection is required for this test.

AUDIBLE ANNUNCIATION TEST — Test # 2

Both the variable pitch, audible pulse-tone, and audible alarms are annunciated by the Model 340's 8-pitch, 3-volume level audible annunciation system. This test, when initiated, sequentially sounds all of the eight (8) pitches (frequencies) and three (3) volume levels. Carefully listen for tone, pitch and volume changes.

AUDIBLE/VISUAL ALARM TEST — Test # 3

This sequence tests the instrument's alarm functions. The audible alarm tone and the four (4) HI/LO ALARM INDICATORS are simultaneously activated for a period of approximately five (5) seconds. Audible and visual observation is required.

CONTROL KEY TEST — Test # 4

This test checks the functionality of the front panel control keys, excluding the POWER ON/OFF KEY. Once initiated, the operator must press the control keys, one at a time, in the following order: ALARM OFF, OXYGEN SATURATION ALARM, INCREMENT, DECREMENT, and PULSE RATE ALARM. **Do NOT press the POWER ON/OFF KEY at this time as it will power the unit off.** An internal software routine waits for a signal to be received from each of the keys. A unique number indicating the internal memory address for each key will be displayed. Observe the changing values to ensure proper reception of each key's signal.

SENSOR TEST — Test # 5

This test verifies the functionality of the sensor, the oximeter's LED driver circuit, and the oximeter's light-detection circuit. This occurs by the emission of sensor light at a preset frequency and level, and the monitoring of the received signal from the sensor detector.

NOTE: An operational sensor must be connected to the oximeter to perform the Sensor Test.

SERIAL COMMUNICATIONS PORT TEST — Test #6

This test is used in the factory only and cannot be accessed by the user after production.

REFERENCE VOLTAGE TEST — Test # 7

It takes 10 seconds to determine "Pass" or "Fail," verifying the unit's internal reference voltage. A failure is indicated by a display of Err 7, and a pass is indicated by the next test being performed. If a failure is indicated, refer to the PALCO Labs Warranty for servicing instructions.

ANALOG OUTPUT TEST — Test #8

The use of a voltmeter is required to perform this test. First, connect one lead to pin #6 (saturation analog output) and the common output lead to pin #7 (ground signal common). Once initiated, each depression of the ALARM OFF KEY tests the three (3) saturation values, which are displayed in the left window in ascending order. Observe the meter display to confirm a proper operation as listed below. Then connect the first lead pin #3 (pulse rate analog output) to test the three (3) pulse rate values as they are displayed in the right window.

%SpO_2		Pin #6	BPM		Pin #3
0%	=	0.000V ± .001	0	=	0.000V ± .001
50%	=	0.500V ± .010	125	=	0.500V ± .010
100%	=	1.000V ± .020	250	=	1.000V ± .020

INTERNAL MEMORY TEST — Test # 9

Upon initiation, this test checks each location of the oximeter's memory. If all locations test to be functional, the numeral 128 will be displayed.

SET-UP TEST — Test # 10

This test alternately displays %SpO_2, pulse rate and internal circuitry set-up values. As with normal monitoring, initiate the test with a sensor applied to a subject. The instrument will perform normal set-up and monitoring functions, and will periodically display single digit set-up numbers — zero (0) for thin tissue, one (1) for medium tissue, or two (2) for thick tissue. This test can only be exited by powering off the instrument.

3.6 CLEANING INSTRUCTIONS

All PALCO Labs Model 300 Series Pulse Oximeter can be wiped clean with isopropyl alcohol or glutaraldehyde. Avoid caustic or abrasive cleaners that will mar the enclosure or keypad. Use extra care when cleaning the red display window to avoid scratching the finish.

WARNING: Do not clean the instrument while it is in operation.

3.7 TROUBLESHOOTING

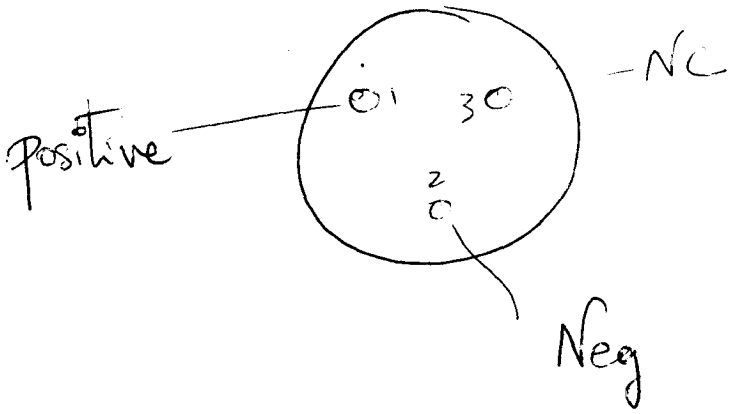
Problem	Possible Causes
Err 5	Improper sensor application; area of sensor application too opaque; sensor problem
Err 135	Ambient light too bright, direct light onto sensor
Err 1,1 1,13,16,17,18	Internal failure of pulse oximeter
bAt LO	Low battery condition
Err 20	Internal EEPROM failure
Warble Tone (Model 340)	Data transmission failure

NOTE: There are no user-serviceable parts or adjustments inside the instrument.

WARNING: Do not attempt to open the instrument case — doing so will void the Warranty. Always refer to the Warranty for service instructions.

AC Adapter Connector

Pin View from outside



4. EQUIPMENT SPECIFICATIONS

4.1 OXYGEN SATURATION AND PULSE RATE

Display	Two 3-digit, 7-segment LED characters 1.0 cm. (0.4 in.) in height	
Resolution	$\%SpO_2$:	1%
	Pulse:	1 BPM
Range	$\%SpO_2$:	0-100%
	Pulse:	32-250 BPM
Accuracy	$\%SpO_2$:	100-70%, ± 2%; 69-60%, ± 3%; Less than 60%, unspecified
	Pulse:	32-250 BPM, ± 2

4.2 ALARMS

Model 340

High $\%SpO_2$	71-100%
Low $\%SpO_2$	70-99%
High Pulse	31-230 BPM
Low Pulse	30-229 BPM

4.3 GENERAL

Size (L x W x H)		19.05 cm. x 8.89 cm. x 3.5 cm.
		(7.5 in. x 3.5 in. x 1 3/8 in.)
Weight	Model 300	439 gm. (15.5 oz. w/ batteries)
	Model 305	453 gm. (16.0 oz.)
	Model 305A, 305AC, 340	496 gm. (17.5 oz.)

4.4 SENSORS

PALCO Labs opto-plethysmographic pulse oximeter sensor with RJ12 connector and extension cable lengths 1.2 or 2.4 meters (4 ft. or 8 ft.)

Red Light Wavelength	660 nm @ 565 µW
Infrared Light Wavelength	910 nm @ 1.8 nW

4.5 POWER SOURCE

4.5.1 Model 300

Battery Type	Six (6) type "AA" alkaline batteries [6 x LR6]
Battery Life	Approximately sixteen (16) hours of continuous operation

4.5.2 Model 305, Model 305A, Model 305AC, Model 340

Battery Type	Rechargeable Nickel-Cadmium (NiCad) battery
Battery Life	12 hours of continuous operation
Power Adaptor Type	Radionic SW15100-PI.
Power Adaptor Input	100-250 V AC 50/60 Hz 0.5 A
Power Adaptor Output	1.5 V DC 1.0 A

4.6 ENVIRONMENTAL CONDITIONS

Acceptable Conditions for Operating, Storage, and Transport:

Atmospheric Pressure	770 to 282.45 mm Hg
	1026 hPa to 377 hPa
	(-500 ft. to 25,000 ft.)
Relative Humidity	5 to 95% (noncondensing)
Operating Temperature	0° to 40° C (32° to 104° F)
Storage & Transport Temperature	-30° to 65° C (-22° to 149° F)

4.7 EQUIPMENT CLASSIFICATION

The PALCO Model 300 Series Pulse Oximeters are classified according to CAN/CSA C22.2 No. 601.1, EN 60601-1, and UL2601-1:

Type of protection against electric shock:

Model 300: INTERNALLY POWERED.

Model 305, 305A, 305AC, 340: CLASS I AND INTERNALLY POWERED. TYPE BF APPLIED PARTS.

Degree of protection against harmful ingress of water:

IPX 0 ACCORDING TO IEC 529.

Degree of safety of application in the presence of a Flammable Anesthetic Mixture with air, or with oxygen or nitrous oxide:

THIS EQUIPMENT IS NOT SUITABLE FOR USE IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE.

Mode of operation:

CONTINUOUS OPERATION

For pulse oximetry with the Models 305A and 305AC, please refer to the manufacturer of the data receiving devices.

5. ORDER INFORMATION

5.1 PRODUCT INFORMATION

Part Number	Description
POX010-300	**Model 300** Hand-Held Pulse Oximeter
POX010-305	**Model 305** Hand-Held Pulse Oximeter w/Rechargeable Battery
POX010-305A	**Model 305A** Hand-Held Pulse Oximeter w/Rechargeable Battery, Serial and Analog Output
POX010-305AC	**Model 305AC** Hand-Held Pulse Oximeter w/Rechargeable Battery, Serial and Analog Output
POX010-340	**Model 340** Hand-Held Pulse Oximeter w/Alarms, Rechargeable Battery, Serial and Analog Output

For Sensors and Accessories, please refer to addendum.

5.2 CONTACT/CUSTOMER SERVICE INFORMATION

For information on any other PALCO Labs products, visit the PALCO Labs home page on the web at www.palcolabs.com, or contact us at:

Customer Service
8030 Soquel Avenue
Santa Cruz, CA 95062-2032, USA

Returns Department
340 El Pueblo Drive, Ste. F
Scotts Valley, CA 95066-4219, USA

Phone
1-800-346-4488 or
(831) 476-3151

Fax
(831) 476-1114

E-mail
info@palcolabs.com

7. DECLARATION OF CONFORMITY

Manufacturer:	PALCO Labs, Inc.
Address:	8030 Soquel Avenue Santa Cruz, CA 95062-2032, USA
Product Designation:	Pulse Oximeter
Type, Model:	PALCO Models 300, 305, 305A, & 340
Year of Manufacture:	1998

We herewith declare that the above mentioned product complies with the requirements of EC Directive 93/42/EEC according to the following:

93/42 EEC Annex I - Essential Requirements
93/42/EEC Annex II - Full Quality Assurance System

The Authorized Representative for PALCO Labs in the European Economic Community is:

Medical Device Safety Service
MDSS GmbH
Burckhardtstr.1
D-30163 Hannover
Germany

The CE mark will be affixed on the above mentioned devices based on Directive 93/42/EEC.

Linda Jo Kaminar — 5/9/98

Linda Jo Kaminar, Regulatory Affairs Coordinator — Date